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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,227	01/25/2005	Rosanne Bonjouklian	X-13980	6841

25885 7590 02/22/2007

ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER	
CHENG, KAREN	
ART UNIT	PAPER NUMBER
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/22/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/22/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/522,227	BONJOUKLIAN ET AL.	
	Examiner	Art Unit	
	Karen Cheng	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) 18-23 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2 and 17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/25/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-27 are currently pending in the instant application and subject to the following restriction requirement

Lack of Unity Requirement

Claims 1-27 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision set forth in PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). PCT Rule 13.2 further states unity of invention as referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Special technical features, as defined in PCT Annex B, Part 1(b), include those technical features which define a contribution over the prior art.

PCT Annex B, Part 1(e) provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-4, 17 and 24-27 drawn to compound of formula I wherein all the variables are as defined.

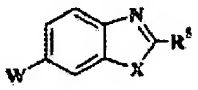
Group II: Claims 18-21, drawn to a method of inhibiting growth of a susceptible neoplasm comprising administering a compound of formula I.

Group III: Claims 18-19 and 23, drawn to a method of treating rheumatoid arthritis comprising administering a compound of formula I.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 CFR 1.475(a), **Groups I-III** lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features. . .those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-III** is a 2,3,5-substituted benzimidazole



I wherein X is N. This technical feature is not a special technical feature because it fails to define a contribution over the prior art (*see* Kai *et al*, CA 125:247806, 1994). Therefore, Claims 1-27 are not so linked as to form a single general inventive concept, and there is lack of unity of invention. The variables vary extensively and, when taken as a whole, result in different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, *or* a method of use.

Furthermore, with respect to **Groups I-III**, even if unity of invention under 36 CFR 1.475(a) is not lacking, a national stage application, under 37 CFR 1.475(b), containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to only one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or
(4) A process and an apparatus or means specially designed for carrying out said process; or

(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specially designed for carrying out said process.

Moreover, according to 37 CFR 1.475(c), if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case, the claims are drawn to a product and more than one use (i.e. treatment of tumor or arthritis). According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

During a telephone conversation with Robert Titus on February 14, 2007 a provisional election was made *with* traverse to prosecute the invention of Group I, claims 1-4, 17 and 24-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

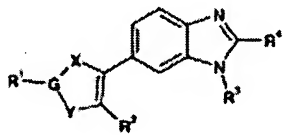
Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/421,939, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically claims 1 and 17 are not entitled to the filing date of the prior application 60/421,939 as subject matter

found in the instant claims does not find support in Application No. 60/421,939. For example, the substituent W wherein W is (iii)-(vi) and (viii)-(x) does not find support in the prior application 60/421,939 as W is defined as



I wherein X-G-Y is –N=C-N(R^{10})-, -N(R^{11})-C=N-, or –S-C=N-, which only supports compounds of the instant application wherein W is (i), (ii) and (vii) as defined in the instant application.

Accordingly claims 1 and 17 are not entitled to the benefit of the filing date of prior Application No. 60/421,939.

Information Disclosure Statement

Applicant's Information Disclosure Statement filed on 11/12/03 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The title of the invention does not correspond to what is set forth in the oath.

Objections: Content of Specification

The specification does not incorporate cross reference to related applications. The specification should contain the following sections below, as applicable:

b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

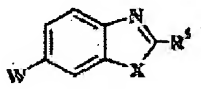
The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Rejection I:

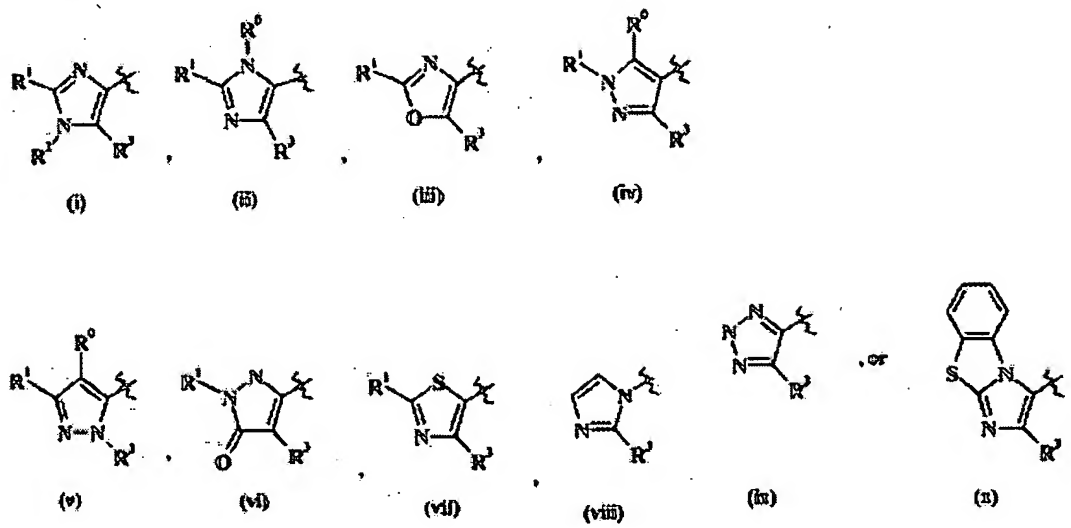
Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kai *et al* (see CA 125:247806, 1994).

Applicants' instant elected invention in claim 1 teach compounds of formula I



wherein I

W is



R^0 is hydrogen and other substituents as defined in claims, R^1 is hydrogen and other substituents as defined in claims, X is N(R^4) or S;

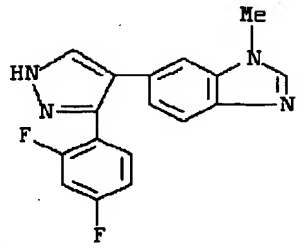
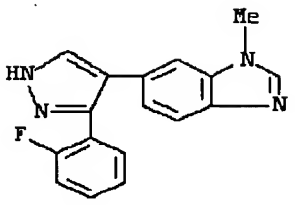
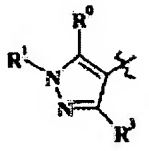
R^3 is thienyl or phenyl optionally substituted with one to two substituents independently selected from the group consisting of halo, C_1-C_4 alkyl, C_1-C_6 alkoxy, and trifluoromethyl;

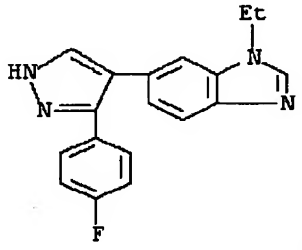
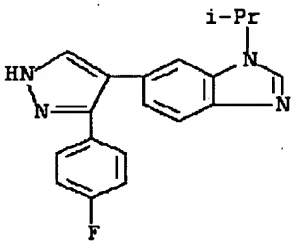
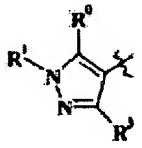
R^4 is hydrogen, (C_1-C_6 alkyl)sulfonyl, or (C_3-C_6 cycloalkyl)sulfonyl; or (C_1-C_6 alkyl)$_2$N-sulfonyl;

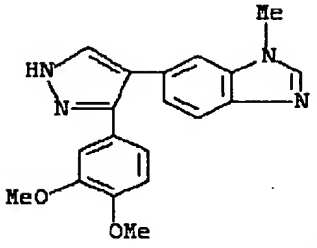
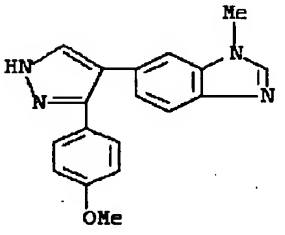
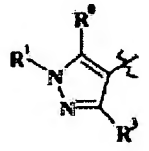
R^5 is halo, hydrogen, or $-NR^9R^{10}$;

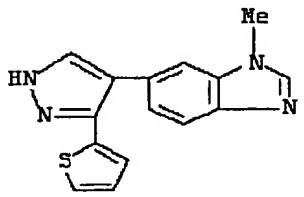
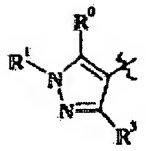
Determination of the scope and content of the prior art (MPEP §2141.01)

Kai *et al* teach the compounds shown below:

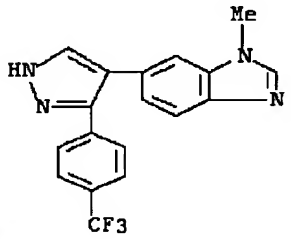
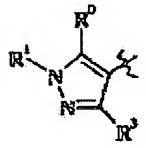
a)  and  wherein R^5 = H, X = NR^4, R^4 = methyl, W = (iv)  , R^0, R^1 = H and R^3 = phenyl substituted with halo.

b)  and  wherein R^5 = H, X = NR^4, R^4 = ethyl or isopropyl, W = (iv)  , R^0, R^1 = H and R^3 = phenyl substituted with halo.

c)  and  wherein R^5 = H, X = NR^4, R^4 = methyl, W = (iv)  , R^0, R^1 = H, and R^3 = phenyl substituted with C_1-C_4 alkoxy.

d)  wherein R^5 = H, X = NR^4, R^4 = methyl, W = (iv)  ,

R^0, R^1 = H, and R^3 = thienyl.

e)  wherein R^5 = H, X = NR^4, R^4 = methyl, W = (iv)  ,

R^0, R^1 = H, and R^3 = phenyl substituted with trifluoromethyl.

Ascertainment of the different between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Kai *et al* and the instantly claimed compounds is that the compounds of Kai *et al* are directed towards tertiary amine compounds rather than the secondary amine compounds that are claimed in the instant invention.

Finding of prima facie obviousness- rational and motivation (MPEP §2142-2143)

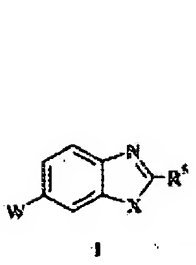
Kai *et al* is analogous art because the compounds found in the art possess similar activity. In Ex part Bluestone, 135 USPQ 199, secondary and tertiary amines are stated to be interchangeable. Additionally, it is obvious to replace a hydrogen atom with a lower alkyl group on a nitrogen atom. Note Ex parte Weston, 121 USPQ 428 and In re Hoeksema, 158 USPQ 596. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional compounds useful for the same purposes would be obtained. In the absence of

unexpected results, one skilled in the art would expect that the instant claims which are analogous to the compounds of Kai *et al*, i.e. secondary amine vs tertiary amine, is prima facie. In the instant case, the claimed compounds and pharmaceutical compositions would have been rendered obvious by the structurally similar compounds of the reference.

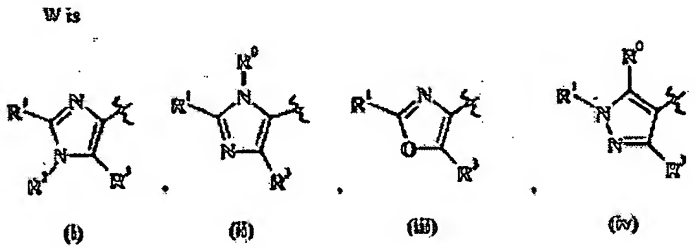
Rejection II:

Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaster et al (see WIPO Pub No. 2003/042211, published 11/14/2002). It is noted that appicant's work discussed below was not found within U.S. Provisional Application 60/421,939. Thus this matter has been given the priority date of the 371 of International Application No. PCT/US03/19890, filed on 07/31/2003 rather than the priority date of U.S. Provisional Application 60/421,939, filed on 10/28/2002.

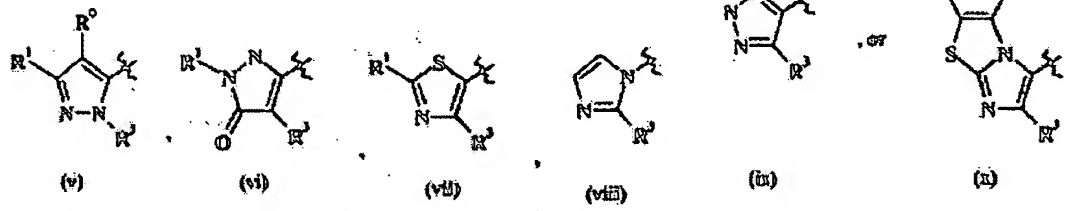
Applicants' instant elected invention in claims 1 and 17 teach compounds of formula I



wherein W is



(i) (ii) (iii) (iv)



(v) (vi) (vii) (viii) (ix) or (x)

R^0 is hydrogen and other substituents as defined in claims, R^1 is hydrogen and other substituents as defined in claims, X is $N(R^4)$ or S;

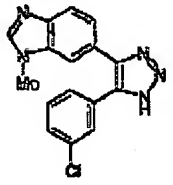
R^3 is thienyl or phenyl optionally substituted with one to two substituents independently selected from the group consisting of halo, C_1-C_4 alkyl, C_1-C_4 alkoxy, and trifluoromethyl;

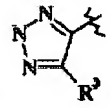
R^4 is hydrogen, (C_1-C_4 alkyl)sulfonyl, or (C_3-C_8 cycloalkyl)sulfonyl; or (C_1-C_6 alkyl)$_2$N-sulfonyl;

R^5 is halo, hydrogen, or $-NR^9R^{10}$; and

pharmaceutical formulation comprising said compound.

Determination of the scope and content of the prior art (MPEP §2141.01)

Gaster *et al* teach compound of  wherein R^5 = H, X = NR^4, R^4 = methyl,

W = (ix)  , R^3 = phenyl substituted with halo (see example 18, p. 20) and pharmaceutical composition comprising said compound (see claim 7, p. 24).

Ascertainment of the different between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Gaster *et al* and the instantly claimed compounds is that the compounds of Gaster *et al* are directed towards tertiary amine compounds rather than the secondary amine compounds that are claimed in the instant invention.

Finding of prima facie obviousness- rational and motivation (MPEP §2142-2143)

Gaster *et al* is analogous art because the compounds found in the art possess similar activity. In Ex part Bluestone, 135 USPQ 199, secondary and tertiary amines are stated to be interchangeable. Additionally, it is obvious to replace a hydrogen atom with a lower alkyl group on a nitrogen atom. Note Ex parte Weston, 121 USPQ 428 and In re Hoeksema, 158 USPQ 596. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional compounds useful for the same purposes would be obtained. In the absence of unexpected results, one skilled in the art would expect that the instant claims which are analogous to the compounds of Gaster *et al*, i.e. secondary amine vs tertiary amine, is prima facie. In the instant case, the claimed compounds and pharmaceutical compositions would have been rendered obvious by the structurally similar compounds of the reference.

Double Patenting

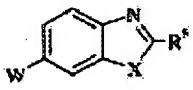
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

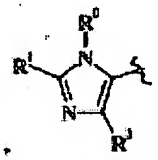
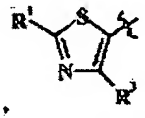
F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of copending Application No. 10/597359. Although the conflicting claims are not identical, they are not patentably distinct from the pending claims because applicants are claiming compounds of the following structure

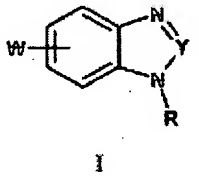
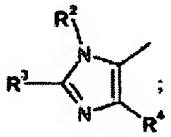
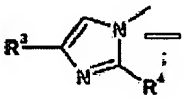
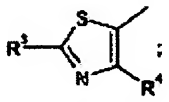


(I) wherein W is  (ii)  (vii)  (viii); X is NR^4 where R^4 is hydrogen; R^5 is hydrogen or $-NR^9R^{10}$ wherein R^9 is hydrogen or C_1-C_4 alkyl, R^{10} is

hydrogen, C_1-C_4 alkyl or benzyl; R^0 is hydrogen or C_1-C_6 alkyl, R^1 is hydrogen, C_1-C_6 alkyl, trifluoromethyl or phenyl optionally substituted with one to three substituents independently selected from halo or trifluoromethyl or

Alternatively R^0 and R^1 may be taken together to form a fully saturated C_3-C_4 carbon chain or a fully unsaturated C_3-C_4 carbon chain optionally substituted with halo or C_1-C_4 alkyl;

; R^3 is phenyl optionally substituted with one to two substituents independently selected from the group consisting of halo and trifluoromethyl, and a pharmaceutical formulation comprising said compound and a pharmaceutically acceptable carrier, diluent, or excipient.

Conflicting claims 1-3, and 5 of copending Application No. 10/597359 are drawn to compounds of formula  I wherein W is  (i)  (ii)  (v) ; Y is C-R^1; R^1 is hydrogen, amino or methyl; R is hydrogen; R^2 is hydrogen, C_1-C_6 alkyl; R^3 is hydrogen, C_1-C_6 alkyl, trifluoromethyl, or phenyl optionally substituted with one or two substituents independently selected from the group consisting of halo or trifluoromethyl or

R^2 and R^3 taken together form either the group $-(CH_2)_n-$ where n is 2 or 3 or the group -CH=CH-;

; R^4 is phenyl optionally substituted with one or two substituents independently selected from the group consisting of halo and trifluoromethyl, and a pharmaceutical formulation

comprising said compound and a pharmaceutically acceptable carrier, diluent, or excipient

The difference between the claims at issue and the conflicting claims is found within the scope of the claims. The instant claims are drawn to compounds that can also fall within the scope of the conflicting claims. Though the formula of the instant and conflicting claims are different, preferences towards compounds that have the same W is found within claim 2 of the conflicting claims and claim 2 of the instant claims. Other variables found in the instant claims (R^0, R^1, R^3, R^4, R^5) can be found within the corresponding variables (R^2, R^3, R^4, R, R^1) of the conflicting claims.

Therefore, it would have been obvious to one of ordinary skill in the art, when faced with the conflicting claims of Application No. 10/597359 to synthesize applicants' instantly claimed compounds as kinase inhibitors since compounds of similar scope had been administered for the same use. The motivation would be the expectation of success in use of applicants' compounds for inhibition of kinases.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REBECCA ANDERSON
PATENT EXAMINER

Karen Cheng
Patent Examiner, AU 1626

Joseph McKane
Supervisory Patent Examiner, AU 1626